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P01/7700 0.00-0213596.0

Request for grant of a patent

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The Patent Office

Cardiff Road
Newport
South Wales
NP10 8QQ

1. Your reference

RRH/LAH/MediCath

2. Patent application number
(The Patent Office will fill in this part)

0213596.0

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

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Patents ADP number *(if you know it)*

7532237001

7532245001

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

IMPROVEMENTS IN AND RELATING TO CATHETER CONTROL

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Wynne-Jones Laine & James
22 Rodney Road
Cheltenham
Gloucestershire GL50 1JJ

Patents ADP number *(if you know it)*

1792001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or

b) there is an inventor who is not named as an applicant, or

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Continuation sheets of this form	
Description	15
Claim(s)	–
Abstract	– DML
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Priority documents	–
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Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	–
Request for preliminary examination and search *(Patents Form 9/77)*	–
Request for substantive examination *(Patents Form 10/77)*	–
Any other documents *(please specify)*	–

11. I/We request the grant of a patent on the basis of this application.

Signature [signature] Date 14.06.2002

Wynne-Jones Lainé & James

12. Name and daytime telephone number of person to contact in the United Kingdom: Richard Halstead - 01242 515807

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IMPROVEMENTS IN AND RELATING TO CATHETER CONTROL

Catheter associated urinary tract infections account for a large number of hospital acquired infections. Forty four per cent of hospitalised patients with catheters have been found to develop significant bacteruria within 72 hours of catheterisation. Some of these infections result in complications including pylonephritis, epididymitis, abscess formation and chronic renal failure. This leads to catheter blockage which represents one of the most common complications associated with infections.

Attempts have been made to improve the methods for the prevention, control and treatment of catheter associated infections such as the use of a closed drainage system, strict observance of aseptic techniques in the handling of catheters, the use of cranberry juice drinks and the production of catheters containing antimicrobial substances.

Once an indwelling device, catheter or prosthesis becomes infected, the associated micro-organisms show remarkable resistance to both host defences and antimicrobial agents. Therefore although all of these procedures have been shown to either reduce the incidence or delay the onset of catheter associated infection they have been unable to eradicate it.

Another commonly used method to combat infections and related blockage complications is irrigation of the urinary catheter with various solutions. However, the application of numerous agents using a variety of irrigation methods has resulted in a confusing picture, both in terms of their efficiency and clinical applications.

The building up of encrustation and urease activity results in an increase in urine alkalinity and it has been shown in a study examining the pH encrustation that patients with a mean urinary pH below 6.8 had minute traces of encrustation, while patients above pH 6.8 had considerably more.

It has been found that periodic exercise of the bladder by allowing it to fill and empty normally is beneficial in an otherwise continuous drainage regime in that normal bladder function is preserved and the average pH of the urine is lowered.

Catheter encrustation is often found associated with high urinary pH and the practise of testing the urine for pH level to identify patients most at risk of catheter encrustation has been shown to be beneficial in the management of such patients to avoid encrustation.

Intravascular catheters are also prone to infection and it is recommended that intravascular catheters should be replaced at regular intervals to reduce the risk of catheter related bloodstream infections. The risk of phlebitis and

increased colonisation has been associated with certain types of catheter, however such risk of infection has to be balanced against the practicalities of maintaining intravascular access.

The present invention addresses the problems associated with catheter infection by the provision of an apparatus which monitors and controls the catheter.

According to the invention there is provided apparatus for controlling the operation of a catheter, the apparatus including an inlet for receiving the output end of a catheter and an outlet for discharging liquid from the catheter, valve means between the inlet and the outlet for controlling the flow of liquid through the apparatus, sensing means for sensing one or more properties of the liquid in the apparatus, and control means for controlling operation of the valve means in response to a sensed property of the liquid, such as pressure, and/or in response to a predetermined criteria, such as a time interval having elapsed.

Preferably, the inlet for receiving the output end of the catheter and the outlet for discharging it is an inlet end of a resilient tube, between the other outlet end of which is disposed the valve means, which tube and valve means may be integral. The valve means may conveniently comprise deformable walls of the tube which may be pressed together to thereby wholly or partially close the tube to thereby prevent or inhibit, as the case may be, the flow of liquid from the outlet end.

The invention provides for a device for controlling and managing the operation of a catheter and the measuring, recording, assessing, and the interrogation of the physical and chemical parameters of the contents of the catheter and the downloading of such information to a suitable memory, such as a computer for storing, analysing etc. and the controlled dispensation of appropriate drugs or medicines into the catheter.

The valve means may be actuated by hydraulic, pneumatic, mechanical or electrical means.

The means for assessing, measuring, recording, interrogating and downloading information relating to the contents of the urinary bladder during catheterisation may be electronic.

The means for dispensing appropriate drugs or medicines may be activated electronically or manually.

Where the catheter is to allow urine to be extracted from the bladder of a person, it is preferred that the apparatus is constructed in two parts:-

a) A one use disposable tube with a valve or valves which come into contact with urine, and

b) A reusable electronic control unit which operates the valve or valves, measures pressure, pH value of the urine and any other desired characteristic, and is capable of recording and assessing, downloading and interrogating such data etc.

Where two or more valves are used it is preferred that chambers be provided between them.

Means for sterilising/cleansing the valve chamber/chambers may be provided.

Means for measuring, recording and altering the pH value of the urine may be provided.

The apparatus may conveniently be powered by a renewable or rechargeable battery.

The electronic means for storing, measuring, assessing, recording and early warning may be one or more micro chips.

The disposable tube and/or the reusable part of the apparatus may be provided with a means for attaching to the catheter and the drainage bag.

The disposable tube and the reusable part of the apparatus may be provided with an automatic means of disconnection from the drainage bag if the drainage bag/tube is accidentally pulled. This may be by means of a link which is arranged to be broken when subjected to a predetermined longitudinal force.

In use the disposable tube and valve or valves can fit into the reusable electronic unit and be controlled by an electronic chip. When assembled together into one unit (the urinary control apparatus unit) the valve unit and reusable electronic unit can then automatically control the flow of urine from the bladder and monitor and record desirable information for interrogation. A manual override may be applied to control the flow of urine from the bladder if desired.

The urinary control apparatus can be designed to fit onto the open end of a urinary catheter such as a Foley catheter after the Foley catheter has been installed in the usual way in the bladder. A standard drainage bag may then be fitted to the outlet end of the tube if desired and draining of the bladder can take place in the usual way.

The urinary control apparatus, when supplied with a first electronically controlled valve, which desirably will be placed above the second electronically controlled valve on the catheter side of the control unit, can regulate the flow of urine from the bladder when the sensing means, which may be a pressure switch, detects there is a predetermined pressure of urine in the bladder.

At the predetermined pressure the first electronically controlled valve will open and let out the urine from the bladder after which it will close and urine will once again collect in the catheter tube and the bladder until the pressure builds up ready for the next evacuation. Urine discharged through the urinary control unit may be collected in a standard collecting bag which can be fitted to the distal end of the urinary control apparatus.

When urine passes through a first open valve it may be monitored by the electronic unit e.g. the pH value of the urine may be recorded as well as the frequency and volume etc. Any disadvantageous information recorded may activate an audible warning so that remedial action may be taken.

The urinary control apparatus may be supplied with a second valve which is placed below the first valve on the drainage bag side. This provides a barrier chamber between the two valves in which e.g a slow release anti- bacterial compound or the like may be sited. At a predetermined pressure the first and second valves open and let out urine from the bladder after which they close and urine will once again collect in the catheter tube and the bladder until the pressure builds up ready for the next evacuation. When the second valve is closed the slow release antibacterial compound will then collect in the barrier chamber to provide a barrier between the drainage bag and the urinary control apparatus. This helps to prevent bacteria travelling up into the first chamber and

the catheter lumen. The provision of a chamber with an antibacterial compound or the like can therefore help to prevent infection of the bladder.

An electronic control unit can control the operation of the valves and measure the physical and chemical characteristics of the urine as it passes through the unit. This will supply the data which is required for the early identification of adverse conditions affecting the patient and the catheter e.g. if the pH of the urine is monitored and recorded on a regular long term basis it is possible to identify those patients that are at risk of catheter encrustation and the subsequent risks of catheter blockage, trauma and infection to the wearer.

The benefits of placing the urinary control apparatus between the catheter and the storage bag are as follows:-

a) the control apparatus can fit between an e.g standard Foley catheter and drainage bag such that no user education is necessary.

b) the bladder can be controlled i.e. filled and emptied without patient intervention.

c) the apparatus is suitable for use for a patient who is not conscious or for the elderly confused.

d) drainage of the bladder can be monitored and data relating to urine characteristics measured.

e) bladder drainage can be made automatic such that normal function of the bladder is maintained.

f) the problems associated with infection and crystallisation experienced in continuous drainage can be substantially reduced.

g) the provision of a barrier chamber and the regular flushing of the catheter can mean the possibility of less infection transmitting through the catheter lumen.

h) there can be two seals between the storage bag and the catheter i.e. one at the catheter end (the input urinary control apparatus) and the one way seal adjacent to the collection which is usually installed to prevent backflow from it, to further reduce the incidence of infection.

Substantially complete control of bladder drainage may therefore be possible through the use of the urinary control apparatus. Bladder drainage can be continuous or intermittent according to requirements. The control apparatus can be used for all catheters and drainage bags since the attachments are usually universal. The urinary control apparatus can be made fail-safe in that it

can give warning of failure. In such an event the apparatus can be removed simply by pulling it out of the catheter opening and the bag opening in the same way as the drainage bag fitting is removed from the catheter. The catheter may then be connected to the drainage bag in the usual way and bladder drainage resumed without the control apparatus in place.

In an alternative embodiment of the invention the storage bag may not be attached from the urinary control apparatus and the valve or valves operated manually or electronically in response to pressure sensing if desired. This enables the patient to control and monitor the discharge of urine without the need for carrying a drainage bag.

The urinary control apparatus can therefore be versatile in that a patient in hospital may be fitted with a standard catheter, a urinary control apparatus and a drainage bag. The urinary control apparatus may then be operated in conjunction with a drainage bag whilst the patient requires such treatment. However, when the patient is in a position to be discharged from hospital, or does not require a drainage bag any longer, after some simple user education, the drainage bag may be removed and the catheter and urinary control apparatus left in place. The patient will then be able to operate the discharge of urine manually through the electronic urinary control apparatus and interrogate the electronic monitor to ascertain the pH level etc. of the urine. If the pH level of the urine needs to be altered an appropriate solution may be discharged into the catheter through the electronic control apparatus.

The invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a general arrangement diagram of an inlet and outlet tube, associated valve means and sensing means of the urinary control apparatus;

Figure 2 is a general arrangement diagram of the assembled urinary control apparatus of the invention;

Figure 3 is a general arrangement drawing showing the plan view of the urinary control apparatus of Figure 2;

Figure 4 is a general arrangement diagram of the tube of Figure 1 modified to provide a double valving and sterilisation chamber together with a link arranged to be broken when subject to a predetermined longitudinal force, and

Figure 5 is a general arrangement diagram of urinary control apparatus attached to a typical urinary catheter and a typical urine collection bag.

Figure 1 shows part of a urine control apparatus which includes a resilient tube shown generally at 1, which may be made of e.g silicone. The tube 1

includes at one end a frusto-conical male push connector 2 sized to fit into the cone connection of a typical urinary catheter (not shown). At the other end of the tube 1 is a frusto-conical female connector 3 sized to allow the insertion and retention of a tube from a urine collection bag (not shown). Adjacent to the male connector 2 is a generally disk-shaped location flange 4 provided with a flattened region 5 on one side thereof so as to locate the tube 1 correctly within the urine collection apparatus in a manner to be described. In the mid-region 6 of the tube 1 the walls thereof are deformable to the extent that a pair of actuators 7, when moved towards each other in the direction shown arrowed to the position shown in broken line can squeeze the tube 1 in this region sufficient to effect a valve arrangement by which flow of liquid there through may be prevented or inhibited.

In order to sense the pressure in the tube 1 a pair of pressure sensors or pads 8 can be disposed in the manner as shown to lightly bear against the tube 1 in this region so that the internal pressure of liquid in the tube can then be determined to detect build-up of urine in the bladder of the catheter wearer when the fingers 7 are closed to their position shown in dotted outline.

Above the pressure pads 8 are a pair of electrical contacts 9 emanating from a pH transducer (not shown) built into the wall of the tube 1. This can therefore be used to sense the pH of liquid in the tube via electronic means in a manner to be described.

Referring now to Figures 2 and 3, there is shown the general arrangement of a catheter control apparatus in the form of urine catheter control apparatus comprising, in this embodiment, a housing 10 for containing electronic components including control components for the apparatus, as well as the tube 1, this being retained in place in the housing 10 by the flanged disk 4 being received within a correspondingly shaped recess in the housing 10 in a manner more clearly shown with reference to Figure 3 in which it will be seen that a hinged door 11 can be used to trap the disk 4 and hence the tube 1 in position by bearing up against the flattened portion 5.

A graphic display 12 is provided on a front face of the housing 10, which may be an LCD display to give a visual data output of the apparatus and control buttons shown generally at 13 for actuating electronic components within the housing 10, such as for sensing, actuating and recording purposes.

Figure 4 shows a tube shown generally at 1a similar to the tube 1 of Figure 1 but in this instance instead of having room for a single valve means including a single pair of fingers 7 as shown in Figure 1, there are instead two pairs of fingers 7a and 7b displaced axially along the length of the middle portion 6 of the tube 1a, corresponding other parts of the arrangement to that shown in Figure 1 having corresponding numbering. As can be seen, when the pairs of actuators 7a and 7b are moved inwardly in the direction shown arrowed to the position shown in dotted outline a chamber 14 is formed between them into which may be inserted during the manufacture of the tube 1a a pellet 15, such

as in the shape of an o-ring, of a slow dissolving material capable of providing a sterilising action to any liquid in the chamber, the pellet being formed by commonly available bleaching or sterilising agents. Similarly, one or more other pellets may be releasably held in the tube above the finger 7a and may be capable e.g of releasing acidity into the tube 1a and hence into the catheter lumen to help counter the build-up of alkalinity within the catheter resulting from urease bacteriological activity. The rate of dissolving may be controlled externally as required by providing, for example, a localised heating element in this region of the tube 1a with the pellet being designed to release more or less acidity by varying the heating of the tube 1a and hence the pellet in this region.

As a safety measure a breakable link 16 is provided above the female connector 3 and below the mid-section 6 of the tube 1a, having weakened portions designed to snap when subjected to a pre-determined longitudinal force caused by accidental pulling or tension on the drainage bag and associated tubing.

In Figure 5 there is shown a general arrangement of the urinary control apparatus of this embodiment of the invention attached by its male connector to the female connector 17 of a typical Foley-type urinary catheter 18, and is also attached by its female connector to the tube 19 (only part of which is shown) of a typical urine collection bag 20.

In a second embodiment of the invention there is provided a means for controlling and managing an intravascular device. In this embodiment, the electronic control circuitry and associated tube may be used to measure internal pressure at the site of an intravascular installation and if pressure rises beyond a set limit, e.g the onset of "tissuing", one or more valves may operate automatically to limit the flow and thus reduce the pressure in the intravascular device. At the same time, a warning sound or light may be activated. In this embodiment it is preferred that the pressure sensor be positioned after the valve or valves in order to sense the pressure in the intravascular device, which may typically be a venflon.

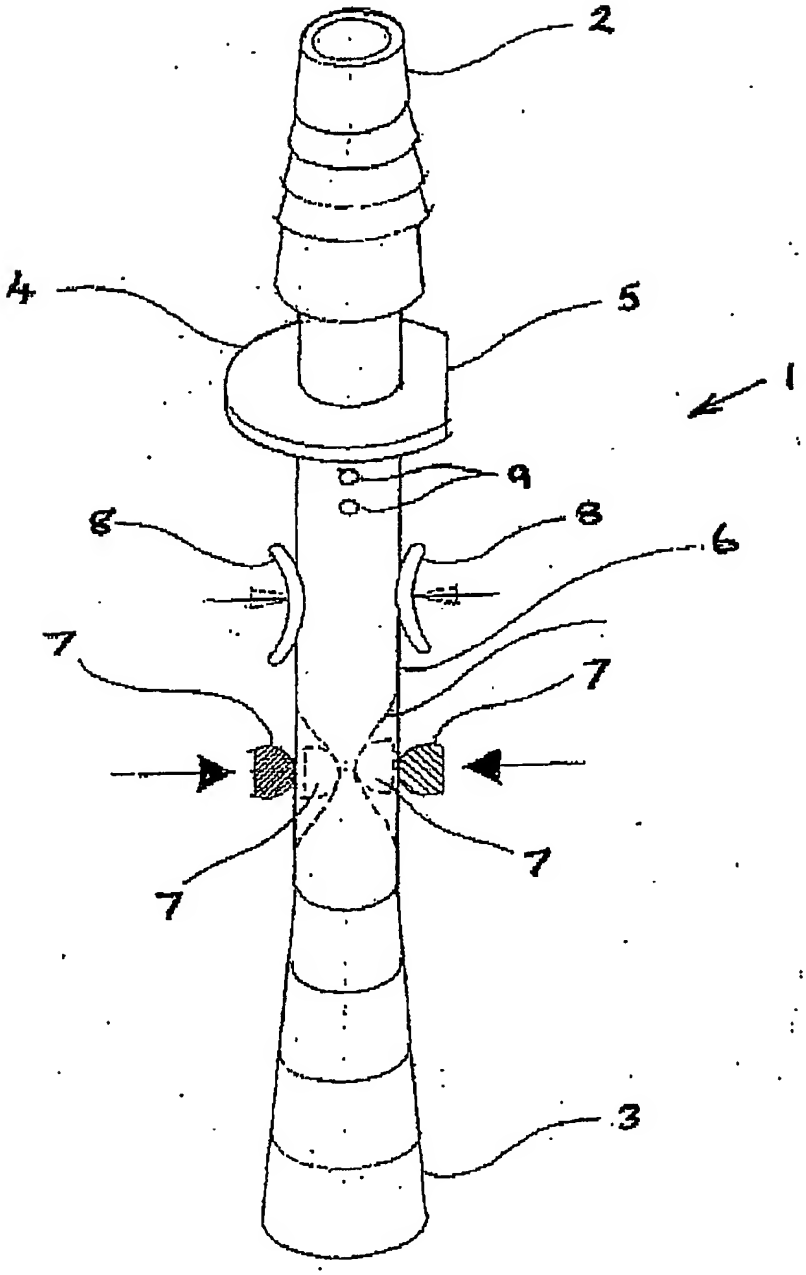

FIGURE 1

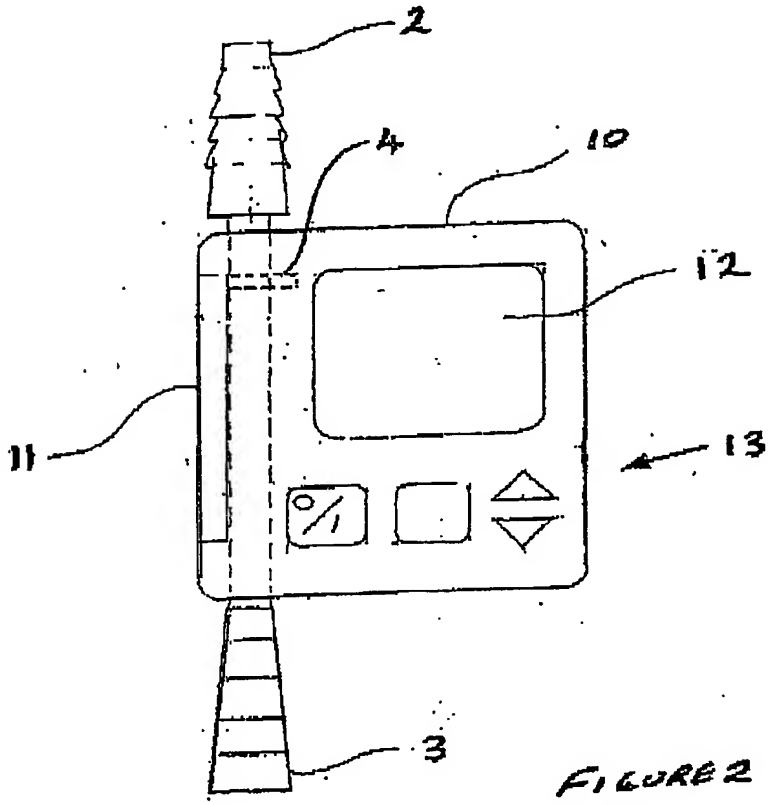

FIGURE 2

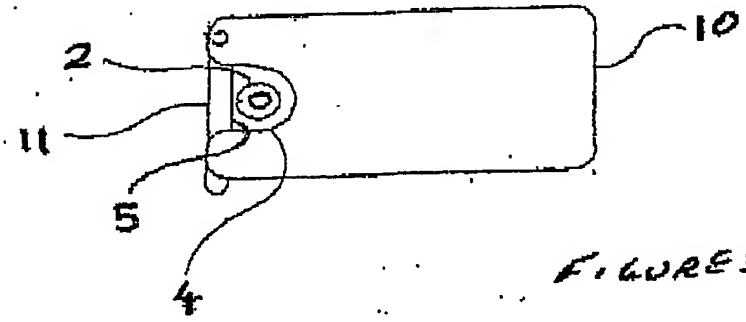

FIGURE 3

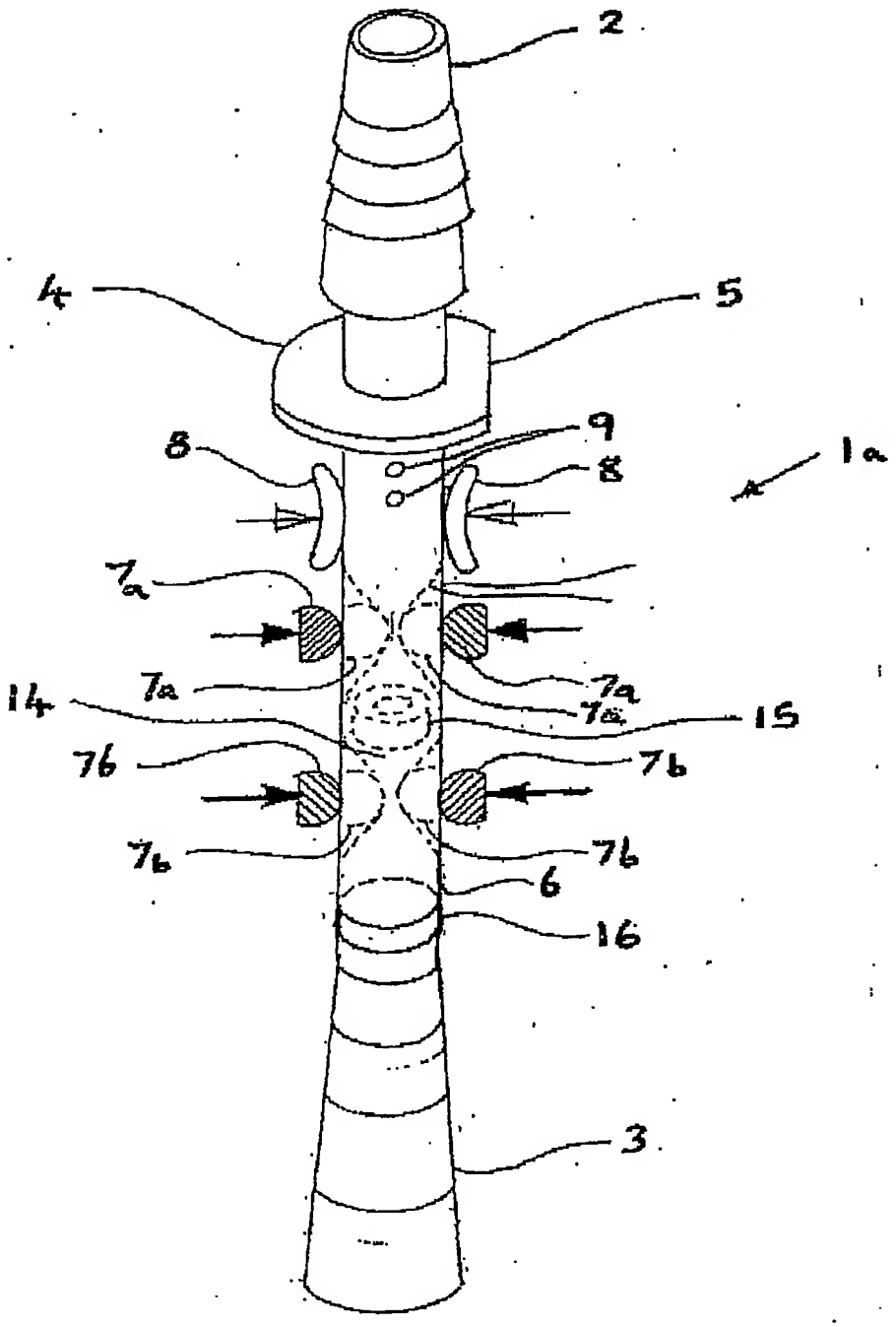

FIGURE 4

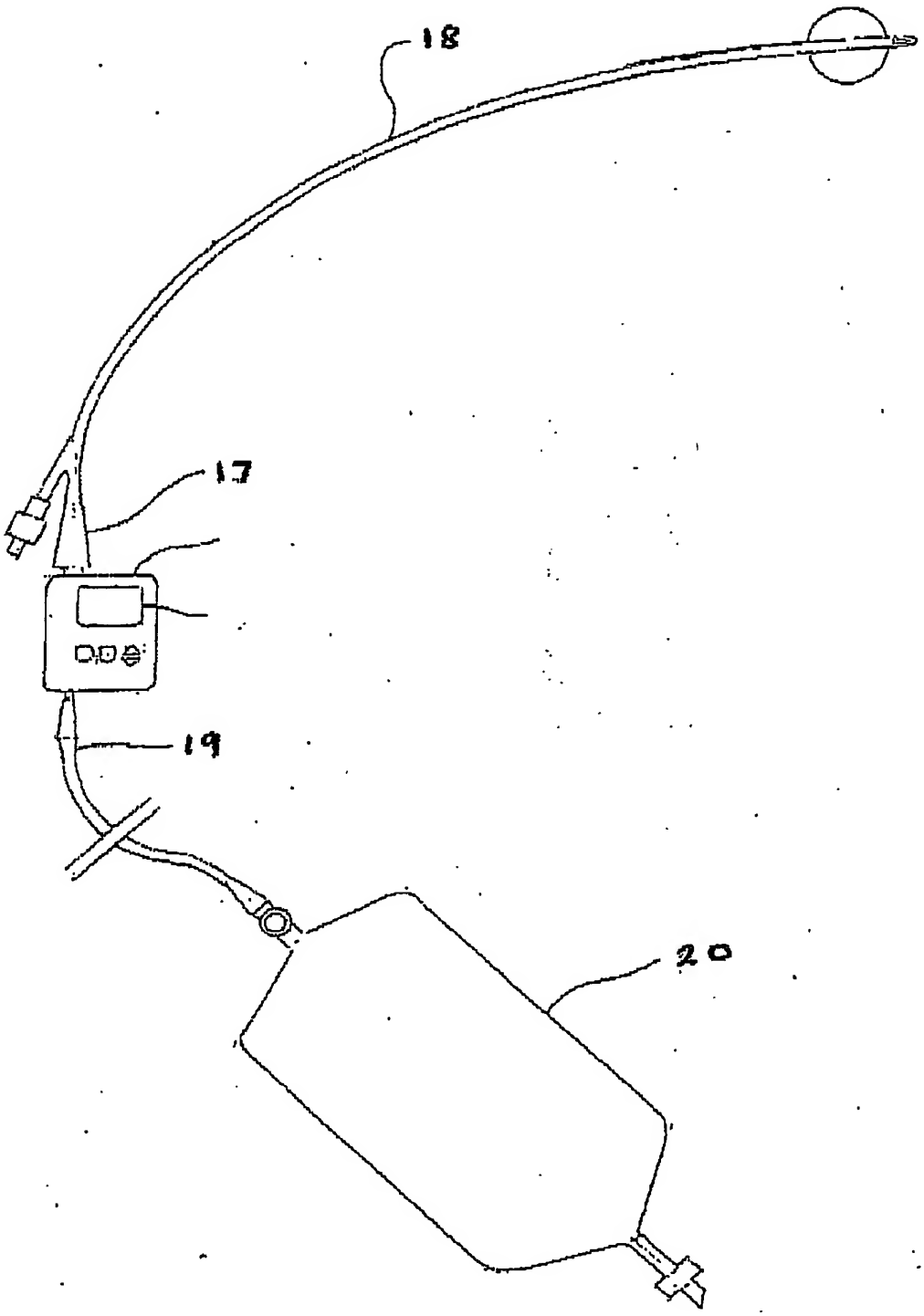

FIGURE 5